Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Efficacy of Photodynamic therapy with topical Indocyanine green in the treatment of Keloidal lesions

Protocol summary

Study aim
Efficacy of Photodynamic therapy with topical indocyanine green in the treatment of Keloidal lesions

Design
clinical trial, pilot study

Settings and conduct
before the therapeutic sessions, small amount of ICG ointment applied in lateral side od arm and the patient being informed not to touch or rinse the place. after 48 hours we look the place for any kind of skin reactions and if there was no skin reactions< the patient is allowed to enter to trial. first a basic photograph of the lesion being taken and the dimensions are determined. lesions being covered with ICG ointment with 1mm thickness on top and 5mm around and its covered with biofilm for 1 hour. then the lesions being wiped off and it goes under photodynamic therapy with source LumaCare with 730 nm probe every 2 weeks and total of 6 sessions. patients being assessed in 6 and 12 weeks after the treatment sessions for any recurrences. the place we do the trial is in dermatology outpatient clinic of imam Reza hospital in Mashhad

Participants/Inclusion and exclusion criteria
The patients with minimum age of 18 years old are being selected based on dermatologist diagnosis as having idiopathic keloids. They have no history of any medical treatments for their lesions in 3 last months. only lesions that are located on trunk, extremities, back and buttock are being selected.

Intervention groups
patients who undergo using indocyanine green ointment and photodynamic therapy

Main outcome variables
determining efficacy of Photodynamic therapy with topical indocyanine green in the treatment of Keloidal lesions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201221049780N1**
Registration date: **2021-03-17, 1399/12/27**
Registration timing: **prospective**

Last update: **2021-03-17, 1399/12/27**
Update count: **0**

Registration date
2021-03-17, 1399/12/27

Registrant information

Name
Sara Fakhraei

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3876 0858

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-21, 1400/02/01

Expected recruitment end date
2021-10-23, 1400/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Efficacy of Photodynamic therapy with topical Indocyanine green in the treatment of Keloidal lesions

Public title
Efficacy of Photodynamic therapy with topical Indocyanine green in the treatment of Keloidal lesions
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
the patients are selected based on dermatologist diagnosis as having idiopathic keloids minimum age for being selected is 18 years old patients have no history of any medical treatments for their lesions at least in 3 months lesions are on trunk, extremities, back and buttock
Exclusion criteria:
any skin disease or abnormality around the lesion for example dermatitis, bacterial or fungal infections pregnancy lactation lesions on face and genitalia history of any medical treatments for their lesions in 3 last months
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **15**
More than 1 sample in each individual
Number of samples in each individual: **2**
2 keloidal lesions of any patients are being selected
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Approval date
2020-12-21, 1399/10/01
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.542

Health conditions studied

1

Description of health condition studied
keloid
ICD-10 code
L91.0
ICD-10 code description
Hypertrophic scar

Primary outcomes

1

Description
improvement of keloidal lesions based on POSAS score
Timepoint
before the trial, every month after starting trial, in 6th and 12th weeks after finishing the trial
Method of measurement
Patient and Observer Scar Assessment Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients under treatment with indocyanine green 0.2% ointment and photodynamic therapy after 1 hour, every 2 weeks for total of 6 sessions
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dermatology Clinic of Imam Reza Hospital of Mashhad City
Full name of responsible person
Ahmad Reza Taheri
Street address

Imam Reza Hospital, Imam Reza square, Ebn_e_sina Avenue
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Sara Fakhraei
Position
dermatology resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available